Statement of
Lawrence R. Deyton, MD, MSPH
Chief Consultant, Public Health Strategic Health Care Group
Veterans Health Administration
Department of Veterans Affairs
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Mr. Chairman and Members of the Committee:

I am pleased to be here today to talk about VA's comprehensive medical programs for veterans with hepatitis C. Accompanying me is Dr. Michael Rigsby, Director of VA's National HIV/Hepatitis C Program.

Mr. Chairman, VA is justifiably proud of its significant accomplishments as the Nation's leader in hepatitis C screening, testing, and treatment. No other health care system cares for more patients living with hepatitis C. VA's leadership role is widely recognized. VA hepatitis C experts serve a number of other federal agencies and advocacy groups as consultants, subject matter experts, and collaborators in the development of educational and public awareness campaigns. VA efforts in hepatitis C have benefited from close collaboration and partnership with Veterans Service Organizations and other veteran and non-profit groups, as well as with other government agencies such as the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Federal Bureau of Prisons (FBOP).

Background

Hepatitis C infection affects over 4 million Americans and is the most common blood-borne infection in the United States. According to the CDC, overall prevalence rate of hepatitis C infection in the U. S. population is estimated to be approximately two percent. The most common risk factors for infection with hepatitis C are injected drug use and history of blood transfusion. Approximately 75-85 percent of those infected with hepatitis C virus develop chronic infection.

Among those with chronic infection, the risk of developing significant liver damage varies considerably, with approximately 10-20 percent developing cirrhosis after 20-30 years of infection.

Antiviral therapy with interferon and ribavirin is indicated for some, but not all, patients with mild to moderate degrees of liver damage from hepatitis C. This treatment has limited efficacy, however, and significant toxicity. Among carefully selected patients, up to 50 percent who complete a 6-12 month course of treatment will have no evidence of active viral replication for at least 6 months after treatment is completed. However, among patients who have factors associated with poor treatment responses (including African Americans, those who are obese, those with genotype 1 infection, and those with ongoing alcohol use), the effectiveness of the treatment is considerably lower. Although our understanding of who might benefit from antiviral drug treatment is changing, only a minority of infected patients has historically been considered suitable for antiviral therapy, and many patients have other medical conditions that make antiviral treatment difficult or unsafe. Therefore, the actual number of infected patients who can be successfully treated using currently recommended antiviral drug therapy is low. In patients who have already developed advanced liver disease, liver transplant may be the best or only available treatment option.

Hepatitis C and Veterans

Reliable blood tests for hepatitis C became available in the early 1990s, and by the mid-1990s several small, VA facility-specific reports had suggested that rates of infection among veterans receiving health care from VA might be higher than those in the general U. S. population. In contrast to these reports, a national study published by the CDC in 1999 found that the infection rate among adult Americans with any lifetime history of military service was 1.7 percent - slightly lower than the 1.8 percent in the overall population. However, veterans who use VA health care services have demographic and socioeconomic characteristics that differ from those of the overall veteran population. These characteristics might be associated with a higher risk of hepatitis C.

In 1999, therefore, in an attempt to understand the magnitude of the hepatitis C problem among veterans receiving VA care, VA asked all veterans having blood drawn for any reason on a single day to consent to hepatitis C testing. In this group of over 26,000 veterans, which was not necessarily representative of all veterans in care but which reflected the most systematic approach to date, 6.6 percent were found to be infected with hepatitis C.

In 2001, Dr. Jason Dominitz of the VA Puget Sound Health Care System began a national hepatitis C prevalence study using rigorous scientific methodology to produce a statistically valid sampling of veterans receiving health care from VA. The purpose of the study was to estimate the prevalence of anti-hepatitis C antibody and evaluate factors associated with infection among users of VA medical centers. The results of the study, scheduled for publication next month, show a prevalence rate of 5.4 percent. Patients in the prevalence study also provided detailed risk information. The risk factors associated with infection were among those already recognized as risks in the general population, including injected drug use and tattoos. No risks specifically associated with military service or military combat were identified.

VA Hepatitis C Programs

Because of the early reports suggesting the possibility that veterans had a high prevalence of hepatitis C infection, VA recognized that hepatitis C infection was of special concern and began a series of steps aimed at identifying veterans with hepatitis C and providing them with appropriate medical evaluation, care, and, as clinically appropriate, the best available antiviral drug therapies. VA established a National Hepatitis C Program in 2001. In creating this Program, VA endorsed a comprehensive public health approach to hepatitis C in the VA health care system. The essential components of this approach include screening and testing, patient and provider education, clinical care, data-based quality improvement, and support for research to improve the health of veterans living with hepatitis C. To support the work of the Hepatitis C Program, resources were also allocated for the development of a national Hepatitis C

Clinical Case Registry, an electronic database of patients with hepatitis C who received care in the VA health care system at any time after January 1, 1996. I will discuss the registry in greater detail later in my statement.

In 2002, the Hepatitis C Resource Center (HCRC) program was launched to take advantage of field-based expertise in hepatitis C care in order to develop and disseminate innovative practices and tools to improve patient care. Under this program, four centers were selected in a national peer-reviewed application process and were given funding for five years. These four centers are located in the Northwest (Seattle/Portland), Minneapolis, San Francisco, and West Haven.

Screening and Testing

VA believes that every veteran at risk for hepatitis C should know his or her infection status so that appropriate education, referral, and medical assessments can take place. Since 1998, it has been VA policy to provide screening for hepatitis C risk factors to all veterans receiving VA health care. With the veterans' informed consent, VA provides testing for those who are found to be at risk. Automated clinical reminders to prompt providers to perform hepatitis C risk assessment were added to VA's national electronic medical record system. From FY 2002 through FY 2004, screening and testing for hepatitis C were adopted as official performance measures.

As a result of these efforts, since 1999, over 4 million veterans in VA care have been screened for risk factors and over 200,000 were diagnosed with hepatitis C infection. During each of the past three years, screening and testing performance has been evaluated using the External Peer Review Program (EPRP), a national yearly review of approximately 50,000 medical records by trained, professional reviewers. The EPRP results have demonstrated steady improvement in screening and testing. In fiscal year 2004, over 98 percent of patients had been screened for risk factors, and over 90 percent of those at risk had been tested for or diagnosed with hepatitis C.

VA continues to refine and enhance the screening and testing processes by encouraging research that examines the epidemiology of and risk factors for

hepatitis C infection among veterans receiving VA health care, and by helping VA health care providers make better use of information available in VA's electronic medical record to supplement patient-reported risk information.

Treatment

Effective hepatitis C treatment must include a wide range of interventions, including education of patients and their families; careful medical assessment (frequently including liver biopsy); identification of and treatment for important co-morbidities (particularly mental health and substance use disorders); prescription of antiviral therapy when appropriate; management and prevention of the complications associated with cirrhosis and end-stage liver disease; and liver transplantation when no other options exist. The VA health care system, as the largest integrated health care system in the United States, is uniquely able to provide this full range of treatment services to patients with hepatitis C.

The rate of progression of liver damage from hepatitis C is variable. Alcohol use is an important modifiable risk factor for accelerated disease progression. VA is actively investigating and piloting simple interventions that will assist patients with hepatitis C to reduce or eliminate alcohol use as a way of maintaining liver health.

Antiviral therapy with various forms of interferon plus ribavirin is appropriate for many patients with mild to moderate liver damage from hepatitis C, and for some patients with more advanced liver disease. However, the treatment duration is 6 to 12 months, and the drugs used frequently produce side effects including fatigue, flu-like symptoms, anemia, and depression. Because of concerns for patient safety and impaired treatment efficacy, patients with histories of mental health disorders or substance abuse were, in the past, routinely denied therapy. VA, however, has taken a leadership role in expanding the population of patients who can be safely treated by investigating and piloting innovative programs that link mental health/substance abuse care and liver specialty care, and by developing educational programs to increase the knowledge and skills of liver specialists in recognizing and managing psychiatric

complications of hepatitis C treatment. Through VA's capitated reimbursement system, the Veterans Equitable Resource Allocation (VERA) system, VA aligns financial incentives to support the care of patients requiring expensive pharmaceutical treatment.

These steps to increase and support antiviral treatment efforts, as well as recent improvements in treatment response rates with newer drugs, have led to increased numbers of veterans receiving treatment. In each of the past two fiscal years, VA has treated approximately 9,000 veterans with antiviral drugs. A number of studies and published reports have indicated that many patients are still not suitable candidates for treatment because of other medical conditions, ongoing hazardous levels of substance abuse, and failure to accept referral to liver specialty care. Still others decline to undergo treatment when it is recommended. These barriers reflect both a complex set of psychosocial issues and the hard reality that current treatments are difficult to tolerate and too often fail to produce the desired outcome of viral eradication. For many patients with only mild liver disease after many years of infection with hepatitis C, the decision to postpone or forego antiviral therapy is appropriate and understandable. For other patients, more pressing medical or psychiatric issues need to be addressed first. For still others, misperceptions or lack of accurate information about hepatitis C disease and treatment need to be addressed. For all these reasons, it is impossible to say what percentage of patients with hepatitis C should be treated, but it is VA's position that all patients need sufficient information and medical evaluation to reach an informed decision about the most appropriate treatment in consultation with a knowledgeable medical professional.

The number of trained liver specialists in the VA health care system, and, indeed, in the United States, is not sufficient to support a system of hepatitis C care that relies exclusively on these highly trained medical specialists. VA believes that efficiency and effectiveness of care is maximized when specialists' time is devoted to those activities that truly require their unique knowledge and skills. Much of the work of patient counseling, medical evaluation, management of treatment side effects, and follow-up for complications of hepatitis C infection

can be performed by generalists or other health care providers. Provider education activities in VA have specifically targeted these groups (i.e. primary care providers, mental health professionals, mid-level practitioners, clinical pharmacists, and addiction counselors) to improve their knowledge, skill, and confidence in providing hepatitis C care.

Improving quality of care

Hepatitis C is a complex, chronic disease with variable natural history, for which diagnostic tests have become available only relatively recently and universally effective treatment is still lacking. Thus, clear indicators and measures of quality in hepatitis C care are not as well established as they are for many other medical conditions in which evidence regarding the efficacy of various interventions has been extensively evaluated and tested. However, even in this relatively new and rapidly evolving field, VA believes that quality of care can be maximized through constant dissemination of new information and best practices, measurement and reporting of meaningful outcome data, and the identification and correction of problems as they occur.

Therefore, a key mission of the HCRC program is to disseminate innovative practices and approaches to hepatitis C care. This work includes the development of guidelines and recommendations based on critical review of the latest research results; creation, testing and dissemination of innovative systems for clinical care delivery; dissemination of information in appropriate educational formats for patients, providers, and community; and the development, testing, and implementation of tools to make information available to providers and patients at a time and in a format that they can use to make decisions about treatment options. In particular, the work of the HCRC program has focused, to a large extent, on ensuring that patients are not inappropriately excluded from any of the available treatment options because of lack of information, understanding, or expertise on the part of the patients or their medical care providers. VA has demonstrated leadership in addressing the needs of hepatitis C patients who also suffer from mental health or substance use disorders. The HCRC programs

are learning that these veterans, who were formerly excluded from anti-hepatitis C therapy, can be safely and effectively treated if given appropriate support and interdisciplinary care. VA's comprehensive health care system (which includes psychiatric care and addiction services) is uniquely able to provide the range of medical care these patients typically require.

The Hepatitis C Case Registry is another important tool for quality improvement and programmatic planning. The objectives of the Registry are to identify VA patients who have been tested or diagnosed as having hepatitis C, describe their clinical status, track their use of clinical services, and improve the quality and efficiency of VA hepatitis C care. Patients are automatically added to the Registry based on either diagnostic codes or results from blood tests for hepatitis C. Through the end of FY 2004, over 273,000 unique patients had been added to the Registry. Of these, 184,067 had at least one VA inpatient admission or outpatient encounter in FY 2003.

Research

VA's Biomedical Laboratory Research and Development Service (BLR&D) and Clinical Science Research and Development Service (CSR&D) have provided funding for studies on hepatitis C that are important to advancing our understanding of hepatitis C among veterans. Since 1995, VA has funded a range of projects that address the prevalence and demographics of hepatitis C virus (HCV) infection in veterans, basic virus-cell interactions, development of improved diagnostic tests for HCV, clinical studies on predictors for HCV treatment response, and development of novel vaccine approaches for the prevention of HCV. One important example of the studies funded by BLR&D/CSR&D is the prevalence study conducted by Dr. Jason Dominitz, which I mentioned earlier in this statement. To take another example of this research, VA's Palo Alto Research Enhancement Award Program (REAP) is dedicated to identifying novel diagnostic and prognostic tests to develop new therapeutic techniques.

VA funding of hepatitis C research has more than tripled since FY 1999, when VA spent $657,013 on 6 projects. In FY 2003, the last year for which statistics are available, VA funded 16 projects with funding of more than $2.4 million. VA investigators also leveraged over $4.1 million in non-VA funding for 104 hepatitis C research projects in that same year.

VA Sharing Lessons Learned

VA is sharing its many lessons and best practices with the larger medical and public health community. We have a comprehensive Web site for providers, patients, and the public that now has over 22,000 visitors and 140,000 page views a month. This website (www.hepatitis.va.gov) showcases the multimedia materials created through VA expertise for patients and health care providers along with extensive listings of other sources of other health information. We have had ongoing collaborations and communication on hepatitis C care and research with NIH, CDC, the FBOP, and others. VA hepatitis C experts have presented findings at national and international medical and scientific meetings and published in peer-reviewed medical journals. For example, last month alone, VA staff led nearly 40 presentations at the annual meeting of the American Association for the Study of Liver Diseases. VA resource centers – our HCRC's are a prime example – are seen as part of the "remarkable transformation of VA Care," to quote the *Annals of Internal Medicine*. Our leadership in the area of hepatitis C is receiving wide recognition. At a roundtable discussion convened by the US Medicine Institute for Health Studies on Federal efforts in hepatitis C, VA's comprehensive public health approach to hepatitis C was held up by that group as "an important model for other clinical and public health programs."

Future Directions

VA recognizes that there is much work yet to be done for veterans at risk for and living with hepatitis C. Although new cases of hepatitis C are currently infrequent, prevention of new infections through education, substance abuse treatment, and further research and surveillance of hepatitis C epidemiology will

remain a high priority. This commitment to disease prevention illustrates VA's role as an important part of the larger U. S. public health effort to decrease chronic viral infections.

For veterans already infected, better strategies are needed to address the modifiable risk factors for hepatitis C-induced liver damage, such as alcohol consumption, obesity, and exposure to other liver pathogens and toxins. VA also will work to expand the percentage of hepatitis C patients who can safely receive and possibly benefit from antiviral drug therapy. Research to develop new drugs and new strategies for using existing drugs will likely remain a high priority for VA and the larger health care community for many years to come. Finally, VA recognizes that many veterans have already lived with chronic hepatitis C for decades and are now developing advanced liver disease with cirrhosis and its many complications, including liver cancer. The rising incidence of liver cancer related to hepatitis C is well documented. VA has recently joined with the National Institutes of Health in conducting an international conference on the topic of liver cancer and will continue to work with researchers, clinicians, and epidemiologists to determine the most effective strategies for screening, diagnosis and treatment of hepatitis-C related liver cancer. VA also has a well-established and active liver transplant program, and the number of liver transplants performed at VA's four liver transplant centers has increased. Hepatitis C is now the most common cause for liver transplant among veterans in VA care.

Conclusion

The commitment of VA leadership to hepatitis C is unwavering. This chronic viral infection is a major concern for veterans in VA care, has the potential to result in significant illness and mortality, and disproportionately affects veterans with multiple other medical problems. Veterans with hepatitis C are among those most dependent on VA medical services and other benefits. In serving these American veterans, VA leads the Nation in hepatitis C care.

Mr. Chairman, this concludes my statement. Dr. Rigsby and I will now be happy to answer any questions that you or other members of the Committee might have.